DELIVERY METHODS AND DEVICES FOR IMPLANTABLE BRONCHIAL ISOLATION DEVICES

REFERENCE TO PRIORITY DOCUMENT

This application claims priority of co-pending U.S. Provisional Patent Application Serial No. 60/429,902 entitled "Implantable Bronchial Isolation Devices", filed November 27, 2002. Priority of the aforementioned filing date is hereby claimed, and the disclosure of the Provisional Patent Application is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to methods and devices for use in performing pulmonary procedures and, more particularly, to devices and procedures for treating lung diseases.

2. Description of the Related Art

Certain pulmonary diseases, such as emphysema, reduce the ability of one or both lungs to fully expel air during the exhalation phase of the breathing cycle. Such diseases are accompanied by chronic or recurrent obstruction to air flow within the lung. One of the effects of such diseases is that the diseased lung tissue is less elastic than healthy lung tissue, which is one factor that prevents full exhalation of air. During breathing, the diseased portion of the lung does not fully recoil due to the diseased (e.g., emphysematic) lung tissue being less elastic than healthy tissue. Consequently, the diseased lung tissue exerts a relatively low driving force, which results in the diseased lung expelling less air volume than a healthy lung.

The problem is further compounded by the diseased, less elastic tissue that surrounds the very narrow airways that lead to the alveoli, which are the air sacs where oxygen-carbon dioxide exchange occurs. The diseased tissue has less tone than healthy tissue and is typically unable to maintain the narrow airways open until the end of the exhalation cycle. This traps air in the lungs and exacerbates the already-inefficient breathing cycle. The trapped air causes the tissue to become hyper-expanded and no longer able to effect efficient oxygen-carbon dioxide exchange.

In addition, hyper-expanded, diseased lung tissue occupies more of the pleural space than healthy lung tissue. In most cases, a portion of the lung is diseased while the remaining part is relatively healthy and, therefore, still able to efficiently carry out oxygen exchange. By taking up more of the pleural space, the hyper-expanded lung tissue reduces the amount of space available to accommodate the healthy, functioning lung tissue. As a result, the hyper-expanded lung tissue causes inefficient breathing due to its own reduced functionality and because it adversely affects the functionality of adjacent healthy tissue.

Lung reduction surgery is a conventional method of treating emphysema. However, such a conventional surgical approach is relatively traumatic and invasive, and, like most surgical procedures, is not a viable option for all patients.

Some recently proposed treatments for emphysema or other lung ailments include the use of devices that isolate a diseased region of the lung in order to modify the air flow to the targeted lung region or to achieve volume reduction or collapse of the targeted lung region. According to such treatments, one or more bronchial isolation devices are implanted in airways feeding the targeted region of

the lung. The bronchial isolation device regulates fluid flow through the bronchial passageway in which the bronchial isolation device is implanted. The bronchial isolation devices can be, for example, one-way valves that allow flow in the exhalation direction only, occluders or plugs that prevent flow in either direction, or two-way valves that control flow in both directions.

The following references describe exemplary bronchial isolation devices: U.S. Patent No. 5,954,766 entitled "Body Fluid Flow Control Device"; U.S. Patent Application Serial No. 09/797,910, entitled "Methods and Devices for Use in Performing Pulmonary Procedures"; and U.S. Patent Application Serial No. 10/270,792, entitled "Bronchial Flow Control Devices and Methods of Use". The foregoing references are all incorporated by reference in their entirety and are all assigned to Emphasys Medical, Inc., the assignee of the instant application.

The bronchial isolation device can be implanted in a target bronchial passageway using a delivery catheter that is placed through the trachea (via the mouth or the nasal cavities) and to the target location in the bronchial passageway. It would be advantageous to develop improved methods and devices for delivering bronchial isolation devices into the lung of a patient.

SUMMARY

Disclosed is an apparatus for deploying a bronchial isolation device in a bronchial passageway in a lung of a patient, comprising an outer shaft having a distal end; a housing coupled to the distal end of the outer shaft and configured to receive the bronchial device; an inner shaft slidably disposed within the outer shaft; and a handle adapted to move the outer shaft relative to both the inner shaft and the handle while the inner shaft remains fixed relative to the handle so as to eject the bronchial isolation device from the housing.

Also disclosed is an apparatus for deploying a bronchial isolation device in a bronchial passageway in a lung of a patient, comprising an outer shaft having a distal end; a housing coupled to the distal end of the outer shaft and configured to receive the bronchial device; an ejection member movably disposed in the housing; and a handle adapted to cause relative movement between the housing and the ejection member so as to eject the bronchial isolation device from the housing. Relative movement between the housing and the ejection member is limited to prevent the ejection member from moving substantially outside of the housing.

Also disclosed is an apparatus for delivering a device into a body passageway, comprising a handle; an outer shaft movably coupled to the handle; an inner shaft slidably disposed within the outer shaft and fixedly coupled to the handle, the handle adapted to move the outer shaft relative to both the inner shaft and the handle while the inner shaft remains fixed relative to the handle; and a sheath attached to the handle and disposed over a portion of the outer shaft such that the outer shaft is free to slide within the sheath.

Also disclosed is a method of deploying a bronchial device in a bronchial passageway in a patient's lung, the method comprising: providing a delivery device having an outer shaft, an inner shaft and a handle; coupling the bronchial isolation device to a housing on a distal end of the outer shaft and a inner shaft; advancing the delivery catheter into the patient's lung with the housing carrying the bronchial device until the housing is positioned in the bronchial passageway; and moving the outer shaft in a proximal direction relative to the inner shaft and the handle while the inner shaft remains fixed relative to the handle to release the bronchial isolation device from the housing.

Also disclosed is a method of deploying a bronchial device in a bronchial passageway in a patient's lung, the method comprising providing a delivery device having an outer shaft, a housing coupled to a distal end of the outer shaft, and an ejection member movably disposed in the housing; advancing the delivery catheter into the patient's lung with the housing carrying the bronchial device until the housing is positioned in the bronchial passageway; and moving the ejection member relative to the housing to eject the bronchial isolation device from the housing, wherein the ejection member is substantially limited from moving outside of the housing.

Other features and advantages of the present invention should be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an anterior view of a pair of human lungs and a bronchial tree with a bronchial isolation device implanted in a bronchial passageway to bronchially isolate a region of the lung.

Figure 2 illustrates an anterior view of a pair of human lungs and a bronchial tree.

Figure 3 illustrates a lateral view of the right lung.

Figure 4 illustrates a lateral view of the left lung.

Figure 5 illustrates an anterior view of the trachea and a portion of the bronchial tree.

Figure 6 shows a perspective view of a bronchoscope.

Figure 7 shows an enlarged view of a distal region of a bronchoscope.

Figure 8 shows a delivery catheter for delivering a bronchial isolation device to a target location in a body passageway.

Figure 9 shows a perspective view of a distal region of the delivery catheter.

Figure 10A shows a plan, side view of the distal region of the delivery catheter.

Figure 10B shows a cross-sectional view of the delivery catheter along line 10B-10B of Figure 10A.

Figure 11A shows the delivery catheter containing a bronchial isolation device in a housing, which is positioned at a location L of a bronchial passageway.

Figure 11B shows the delivery catheter and the deployed bronchial isolation device at the location L of the bronchial passageway.

Figure 12 shows a cross-sectional view of a delivery catheter deployed in a bronchial location that requires the delivery catheter's distal end to bend at an acute angle.

Figure 13 shows a cross-sectional view of the distal end of the delivery catheter with a limited-travel flange fully retracted into the delivery housing.

Figure 14 shows a cross-sectional view of the distal end of the delivery catheter with a limited-travel flange fully extended.

Figure 15 shows a side view of one embodiment of an actuation handle of the delivery catheter.

Figure 16 shows a cross-sectional, side view of the actuation handle of Figure 15 with an actuation member in an initial position.

Figure 17 shows a cross-sectional, side view of a portion of the actuation handle of Figure 15 with the actuation member distal of the initial position.

Figure 18 shows an enlarged view of the distal region of the bronchoscope with the delivery catheter's distal end protruding outward from the working channel.

Figure 19 shows another embodiment of the delivery catheter handle configured for transcopic delivery.

Figure 20 shows the delivery catheter of Figure 19 positioned within the working channel of the bronchoscope with the catheter handle protruding from the bronchoscope.

Figure 21 shows an embodiment of the delivery catheter that includes a deployment sheath.

Figure 22 shows a partial view of the delivery catheter of Figure 21 positioned through an anesthesia adapter.

DETAILED DESCRIPTION

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art to which the invention(s) belong. It should be noted that the various devices and methods disclosed herein are not limited to the treatment of emphysema, and may be used for various other lung diseases.

Disclosed are various devices and methods for delivering one or more bronchial isolation devices (which are sometimes referred to herein as flow control devices) to a location in a bronchial passageway. The bronchial isolation device is delivered to a target location in the bronchial passageway by mounting

the bronchial isolation device in a housing at the distal end of a delivery catheter and then inserting the delivery catheter into the bronchial passageway. Once the housing is positioned at a target location in the bronchial passageway, the bronchial isolation device is ejected from the housing and deployed within the passageway. In the example shown in Figure 1, the distal end of the delivery catheter 110 is inserted into the patient's mouth or nose, through the trachea, and down to a target location in the bronchial passageway 517. For clarity of illustration, Figure 1 does not show the housing in which the device is contained.

The following references describe exemplary bronchial isolation devices and delivery devices: U.S. Patent No. 5,954,766 entitled "Body Fluid Flow Control Device"; U.S. Patent Application Serial No. 09/797,910, entitled "Methods and Devices for Use in Performing Pulmonary Procedures"; U.S. Patent Application Serial No. 10/270,792, entitled "Bronchial Flow Control Devices and Methods of Use"; and U.S. Patent Application Serial No. 10/448,154, entitled "Guidewire Delivery of Implantable Bronchial Isolation Devices in Accordance with Lung Treatment". The foregoing references are all incorporated by reference in their entirety and are all assigned to Emphasys Medical, Inc., the assignee of the instant application.

Exemplary Lung Regions

Throughout this disclosure, reference is made to the term "lung region". As used herein, the term "lung region" refers to a defined division or portion of a lung. For purposes of example, lung regions are described herein with reference to human lungs, wherein some exemplary lung regions include lung lobes and lung segments. Thus, the term "lung region" as used herein can refer, for example, to a lung lobe or a lung segment. Such nomenclature conform to

nomenclature for portions of the lungs that are known to those skilled in the art. However, it should be appreciated that the term "lung region" does not necessarily refer to a lung lobe or a lung segment, but can refer to some other defined division or portion of a human or non-human lung.

Figure 2 shows an anterior view of a pair of human lungs 210, 215 and a bronchial tree 220 that provides a fluid pathway into and out of the lungs 210, 215 from a trachea 225, as will be known to those skilled in the art. As used herein, the term "fluid" can refer to a gas, a liquid, or a combination of gas(es) and liquid(s). For clarity of illustration, Figure 2 shows only a portion of the bronchial tree 220, which is described in more detail below with reference to Figure 5.

Throughout this description, certain terms are used that refer to relative directions or locations along a path defined from an entryway into the patient's body (e.g., the mouth or nose) to the patient's lungs. The path of airflow into the lungs generally begins at the patient's mouth or nose, travels through the trachea into one or more bronchial passageways, and terminates at some point in the patient's lungs. For example, Figure 2 shows a path 202 that travels through the trachea 225 and through a bronchial passageway into a location in the right lung 210. The term "proximal direction" refers to the direction along such a path 202 that points toward the patient's mouth or nose and away from the patient's lungs. In other words, the proximal direction is generally the same as the expiration direction when the patient breathes. The arrow 204 in Figure 2 points in the proximal or expiratory direction. The term "distal direction" refers to the direction along such a path 202 that points toward the patient's lung and away from the mouth or nose. The distal direction is generally the same as the inhalation or

inspiratory direction when the patient breathes. The arrow 206 in Figure 2 points in the distal or inhalation direction.

The lungs include a right lung 210 and a left lung 215. The right lung 210 includes lung regions comprised of three lobes, including a right upper lobe 230, a right middle lobe 235, and a right lower lobe 240. The lobes 230, 235, 240 are separated by two interlobar fissures, including a right oblique fissure 226 and a right transverse fissure 228. The right oblique fissure 226 separates the right lower lobe 240 from the right upper lobe 230 and from the right middle lobe 235. The right transverse fissure 228 separates the right upper lobe 230 from the right middle lobe 235.

As shown in Figure 2, the left lung 215 includes lung regions comprised of two lobes, including the left upper lobe 250 and the left lower lobe 255. An interlobar fissure comprised of a left oblique fissure 245 of the left lung 215 separates the left upper lobe 250 from the left lower lobe 255. The lobes 230, 235, 240, 250, 255 are directly supplied air via respective lobar bronchi, as described in detail below.

Figure 3 is a lateral view of the right lung 210. The right lung 210 is subdivided into lung regions comprised of a plurality of bronchopulmonary segments. Each bronchopulmonary segment is directly supplied air by a corresponding segmental tertiary bronchus, as described below. The bronchopulmonary segments of the right lung 210 include a right apical segment 310, a right posterior segment 320, and a right anterior segment 330, all of which are disposed in the right upper lobe 230. The right lung bronchopulmonary segments further include a right lateral segment 340 and a right medial segment 350, which are disposed in the right middle lobe 235. The right lower lobe 240

includes bronchopulmonary segments comprised of a right superior segment 360, a right medial basal segment (which cannot be seen from the lateral view and is not shown in Figure 3), a right anterior basal segment 380, a right lateral basal segment 390, and a right posterior basal segment 395.

Figure 4 shows a lateral view of the left lung 215, which is subdivided into lung regions comprised of a plurality of bronchopulmonary segments. The bronchopulmonary segments include a left apical segment 410, a left posterior segment 420, a left anterior segment 430, a left superior segment 440, and a left inferior segment 450, which are disposed in the left lung upper lobe 250. The lower lobe 255 of the left lung 215 includes bronchopulmonary segments comprised of a left superior segment 460, a left medial basal segment (which cannot be seen from the lateral view and is not shown in Figure 4), a left anterior basal segment 480, a left lateral basal segment 490, and a left posterior basal segment 495.

Figure 5 shows an anterior view of the trachea 325 and a portion of the bronchial tree 220, which includes a network of bronchial passageways, as described below. The trachea 225 divides at a lower end into two bronchial passageways comprised of primary bronchi, including a right primary bronchus 510 that provides direct air flow to the right lung 210, and a left primary bronchus 515 that provides direct air flow to the left lung 215. Each primary bronchus 510, 515 divides into a next generation of bronchial passageways comprised of a plurality of lobar bronchi. The right primary bronchus 510 divides into a right upper lobar bronchus 517, a right middle lobar bronchus 520, and a right lower lobar bronchus 422. The left primary bronchus 415 divides into a left upper lobar bronchus 525 and a left lower lobar bronchus 530. Each lobar bronchus 517,

520, 522, 525, 530 directly feeds fluid to a respective lung lobe, as indicated by the respective names of the lobar bronchi. The lobar bronchi each divide into yet another generation of bronchial passageways comprised of segmental bronchi, which provide air flow to the bronchopulmonary segments discussed above.

As is known to those skilled in the art, a bronchial passageway defines an internal lumen through which fluid can flow to and from a lung or lung region. The diameter of the internal lumen for a specific bronchial passageway can vary based on the bronchial passageway's location in the bronchial tree (such as whether the bronchial passageway is a lobar bronchus or a segmental bronchus) and can also vary from patient to patient. However, the internal diameter of a bronchial passageway is generally in the range of 3 millimeters (mm) to 10 mm, although the internal diameter of a bronchial passageway can be outside of this range. For example, a bronchial passageway can have an internal diameter of well below 1 mm at locations deep within the lung. The internal diameter can also vary from inhalation to exhalation as the diameter increases during inhalation as the lungs expand, and decreases during exhalation as the lungs contract.

Bronchial Isolation Device Delivery System

As discussed above, the bronchial isolation device is deployed in the bronchial passageway using a delivery catheter 110, which is inserted into the bronchial passageway through the patient's trachea. In one embodiment, the delivery catheter 110 is inserted directly into the trachea and bronchial passageway. In another embodiment, shown in Figure 1, a bronchoscope 120 assists in the insertion of the delivery catheter 110 through the trachea and into the bronchial passageway. The method that uses the bronchoscope 120 is

referred to as the "transcopic" method. According to the transcopic method, the delivery catheter 110 is inserted into the working channel of the bronchoscope 120, which is deployed to the bronchial passageway 517 either before or after the delivery catheter has been inserted into the bronchoscope 120.

As shown in Figures 1 and 6, in an exemplary embodiment the bronchoscope 120 has a steering mechanism 125, a delivery shaft 130, a working channel entry port 135, and a visualization eyepiece 140. Figure 1 shows the bronchoscope 120 positioned with its distal end at the right primary bronchus 510. The delivery catheter 110 is positioned within the bronchoscope 120 such that the delivery catheter's distal end and the attached bronchial isolation device 115 protrude outward from the distal end of the bronchoscope 120, as shown in Figure 1.

Figure 6 shows an enlarged view of the bronchoscope 120, including the steering mechanism 125, delivery shaft 130, working channel entry port 135, and visualization eyepiece 140. In addition, the bronchoscope can also include a fiber optic bundle mounted inside the length of the bronchoscope for transferring an image from the distal end to the eyepiece 140. In one embodiment, the bronchoscope also includes a camera or charge-coupled device (CCD) for generating an image of the bronchial tree. Figure 7 shows an enlarged view of the distal portion of the bronchoscope 120. A working channel 710 (sometimes referred to as a biopsy channel) extends through the delivery shaft 130 and communicates with the entry port 135 (shown in Figure 6) at the proximal end of the bronchoscope 120. The working channel 710 can sometimes be formed by an extruded plastic tube inside the body of the bronchoscope 120. The bronchoscope 120 can also include various other channels, such as a

visualization channel 720 that communicates with the eyepiece 140 and one or more illumination channels 730. It should be appreciated that the bronchoscope can have a variety of configurations and is not limited to the embodiment shown in the figures. For example, in an alternative embodiment, the working channel 710 may be formed of a flexible material and temporarily or permanently attached to the outside of the delivery shaft 130.

Figure 8 shows one embodiment of the delivery catheter 110 for delivering and deploying the bronchial isolation device 115 to a target location in a bronchial passageway. The delivery catheter 110 has a proximal end 810 and a distal end 815 that can be deployed to a target location in a patient's bronchial passageway, such as through the trachea. The catheter 110 has an elongated outer shaft 820 and an elongated inner shaft 825 that is slidably positioned within the outer shaft 820 such that the outer shaft 820 can slidably move relative to the inner shaft 825 along the length of the catheter, as described in more detail below.

The following references describe exemplary delivery devices: U.S. Patent No. 5,954,766 entitled "Body Fluid Flow Control Device"; U.S. Patent Application Serial No. 09/797,910, entitled "Methods and Devices for Use in Performing Pulmonary Procedures"; U.S. Patent Application Serial No. 10/270,792, entitled "Bronchial Flow Control Devices and Methods of Use"; and U.S. Patent Application Serial No. 10/448,154, entitled "Guidewire Delivery of Implantable Bronchial Isolation Devices in Accordance with Lung Treatment". The foregoing references are all incorporated by reference in their entirety and are all assigned to Emphasys Medical, Inc., the assignee of the instant application.

With reference still to Figure 8, an actuation handle 830, is located at the proximal end 810 of the catheter 110. The actuation handle 830 can be actuated

to slidably move the outer shaft 820 in a proximal direction relative to the inner shaft 825 with the inner shaft 825 remaining fixed relative to the actuation handle 830. During such movement, the outer shaft 820 slides over the inner shaft 825. Figure 8 shows a schematic view of the actuation handle 830, which is described in more detail below. Generally, the handle 830 includes a first piece 835 and a second actuation piece 840, which is moveable relative to the first piece 835. The outer shaft 820 of the catheter 110 can be moved relative to the inner shaft 825 by moving the first piece 835 of the handle 830 relative to the second piece 840.

The inner shaft 825 of the catheter 110 can include a central guidewire lumen (not shown) that extends through the entire length of the catheter 110. The central guidewire lumen of the inner shaft 825 is sized to receive a guidewire, which can be used during deployment of the catheter 110 to guide the catheter 110 to a location in a bronchial passageway.

With reference still to Figure 8, a housing 850 is located at or near a distal end of the catheter 110 for holding therein the bronchial isolation device 115. In one embodiment, the housing 850 is attached to a distal end of the outer shaft 820 of the catheter 110 but not attached to the inner shaft 825, which extends axially through the housing. The housing 850 defines an inner cavity that is sized to receive the bronchial isolation device 115 therein.

Figure 9 shows an enlarged, perspective view of the distal portion of the catheter 110 where the housing 850 is located. Figure 10A shows a plan, side view of the distal portion of the catheter 110 where the housing 850 is located. As shown in Figures 9 and 10A, the housing 850 is shaped to receive the bronchial isolation device therein and is open at a distal end and closed at a

proximal end. The inner shaft 825 of the catheter 110 protrudes through the housing 850 and can slidably move relative to the housing 850. An ejection member, such as a flange 910, is attached at or near a distal end of the inner shaft 825. The flange 910 is sized such that it can be received into the housing 850 so that the flange 910 can be withdrawn into the housing 850 to abut a proximal end of the housing. Figures 9 and 10A show the flange 910 positioned outside of the housing 850.

As described below, the ejection member can be used to eject the bronchial isolation device 115 from the housing 850. The housing can be manufactured of a rigid material, such as steel. The housing 850 can also be flexible or collapsible. Although the housing 850 is shown having a cylindrical shape, it should be appreciated that the housing 850 can have other shapes that are configured to receive the bronchial isolation device therein.

In one embodiment, a sizing element 925 is located at or near the housing 850, as shown in Figures 10A and 10B. (For clarity of illustration, Figure 10B does not show the bronchial isolation device 115 mounted in the housing 850 and does not show the inner shaft 825 of the delivery catheter.) The sizing element 925 can be used to determine whether the bronchial isolation device 115 in the housing 850 will fit within a particular bronchial passageway in a working manner. The sizing element 925 comprises one or more extensions, such as first extensions 930a and second extensions 930b that define distances L1 and L2, respectively. That is, the opposed, outer tips of the extensions 930a are separated by a distance L1 and the opposed, outer tips of the extensions 930b are separated by a distance L2. The distance L1 corresponds to the diameter of the larger end of the functional diameter range of the bronchial isolation device

115. That is, the distance L1 is substantially equal to the largest possible diameter for a bronchial passageway in which the bronchial isolation device can be functionally deployed. The distance L2 corresponds to the diameter of the lower end of the functional diameter range of the bronchial isolation device 115. That is, the distance L2 is substantially equal to the smallest possible diameter for a bronchial passageway in which the bronchial isolation device 115 can be functionally deployed. It should be appreciated that the extensions 930 can take on a variety of structures and shapes. For example, Figures 10A and 10B shows the extensions 930 comprising elongate prongs that extend radially outward from the catheter or the housing 850.

In another embodiment, shown in Figure 9, the extensions 930 of the sizing element 925 comprise two or more loops 931a and 931b, which correspond to the extensions 930a and 930b, respectively. Each loop 931 forms an ellipse having a long axis of a predetermined length. In the illustrated embodiment, the loop 931a has a long axis of length L1 that is greater than the length L2 of the long axis of the second loop 931b. Thus, the larger length L1 of loop 931a corresponds to the diameter of the larger end of the functional diameter range of the bronchial isolation device 115. The shorter length L2 of loop 931b corresponds to the diameter of the lower end of the functional diameter range of the bronchial isolation device.

As the delivery catheter 110 is inserted into the bronchial passageway, the sizing element 925 is used to determine whether or not the bronchial passageway is within the functional range of the bronchial isolation device 115. For a bronchial passageway in which the sizing element is positioned, if the opposed tips of the longer extensions 930a (e.g., the diameter loop 931a) cannot

simultaneously contact the wall of the bronchial passageway, then the bronchial isolation device 115 is too small to be implanted in that passageway. In other words, the bronchial passageway is too large for the bronchial isolation device if the tips of the longer extensions 930a cannot simultaneously contact the bronchial wall when the extensions 930a are centrally positioned within the bronchial passageway. If the opposed tips of the shorter extensions 930b can simultaneously contact the wall of the bronchial passageway, then the bronchial isolation device 115 is too large to be implanted in the bronchial passageway in a working manner.

The extensions 930, such as the loops 931, can be constructed of various materials. In one embodiment, the extensions are constructed of wire, etched from a flat plate, or by other methods. The extensions 930 can be made of a flexible material, such as Nitinol, or a polymer or other flexible material, such that the extensions fold down when inserted into or retracted into the working channel of the bronchoscope. In one embodiment, the extensions are manufactured of Pebax, which is a polyether-block co-polyamide polymer. Other flexible resins can be used as well. Other configurations and shapes of the sizing element 925 are contemplated, such as standing struts rather than loops, etc.

In use, the bronchial isolation device 115 is first inserted into the housing 850. The bronchial isolation device 115 can be inserted into the housing according to various methods and devices, some of which are described in U.S. Patent Application Serial No. 10/270,792, entitled "Bronchial Flow Control Devices and Methods of Use", which is assigned to Emphasys Medical, Inc., the assignee of the instant application. After the bronchial isolation device 115 is inserted into the housing, the distal end of the delivery catheter 110 is deployed

into a bronchial passageway via the trachea such that the housing 850 is located at or near the target location in the bronchial passageway, as shown in Figure 11A. Once the delivery catheter 110 and the attached bronchial isolation device 115 are located at the target location, an operator can eject the bronchial isolation device 115 from the housing 850 into the bronchial passageway.

This process is described with reference to Figure 11A and 11B. Figure 11A shows a cross-sectional view of a bronchial passageway 1110 with the deliver catheter 110 positioned therein. The distal end of the delivery catheter 110, including the housing 850, is located at or near the target location L. Once the catheter is positioned as such, an operator actuates the catheter handle 830 to slidably move the outer catheter member 820 in a proximal direction relative to the location L, while maintaining the location of the bronchial isolation device 115, inner shaft 825, and flange 910 fixed with respect to the location L. The proximal movement of the outer shaft 820 causes the attached housing 850 to also move in a proximal direction, while the flange 910 prevents the bronchial isolation device 115 from moving in the proximal direction. This results in the housing 850 sliding away from engagement with the bronchial isolation device 115 so that the bronchial isolation device 115 is eventually entirely released from the housing 850 and implanted in the bronchial passageway at the target location L, as shown in Figure 11B.

During actuation of the actuation handle 830, the outer shaft 820 can undergo tension and the inner shaft 825 undergo compression due to the relative movement of the shafts and possible friction against the proximal movement of the outer shaft 820. This can result in an axial shortening of the inner shaft 825 and an axial lengthening of the outer shaft 820. In order to compensate for this

and to allow the device 115 to be fully ejected from the housing 850, the flange 910 can be configured to over-travel a distance Y beyond the distal end of the housing 850, as shown in Figure 11B. The over-travel of the flange 910 beyond the housing's distal end can create a potential problem during withdrawal of the delivery catheter 110, particularly in situations where the delivery catheter 110 is deployed in a location that requires its distal end to bend at an acute angle. Figure 12 shows such a situation, where the bronchial isolation device 115 is deployed at a location in the bronchial tree 220 that requires the delivery catheter 110 to bend at an acute angle with the flange 910 withdrawn entirely from the housing 850. In such situations, the flange 910 can catch on the tissue of the bronchial wall at a location 1210 inside the bend as the operator pulls the catheter 110 out of the bronchial passageway. This can make it difficult for an operator to remove the delivery catheter 110 from the bronchial passageway and can risk possible damage to the tissue if the operator continues to pull while the flange is caught on the bend.

This problem can be overcome by limiting the travel of the flange 910 relative to the housing 850 such that the flange 910 cannot move outward of the distal end of the housing 850. One way this can be accomplished is by limiting the travel of the inner shaft 825 at the distal end of the catheter 110. Figure 13 shows a cross-sectional view of the distal region of the catheter, showing the inner shaft 825 axially disposed in the outer shaft 820. As mentioned, the flange 910 is attached to the inner shaft 825 and the housing 850 is attached to the outer shaft 820. The inner shaft 825 has a step 1405 and the housing 850 or outer shaft 820 has a stop or ledge 1410. The step 1405 is spaced from the ledge 1410 when the flange 910 is fully withdrawn in the housing 850. As the

outer shaft 820 moves in the proximal direction, the step 1405 eventually abuts the ledge 1410, which acts as a stop to limit any further proximal movement of the outer shaft 820 relative to the inner shaft 825. As shown in Figure 14, the flange 910 is positioned just at the distal end of the housing 850 when the stop position is reached. Thus, the flange 910 and housing 850 have a relative range of travel therebetween.

In one embodiment, the flange 910 is limited from being distally positioned at all past a distal edge of the housing. In another embodiment, the flange 910 can be distally positioned past the distal end of the housing only to the extent that the flange will not catch onto tissue during withdrawal of the delivery catheter. Thus, referring to Figure 11B, the distance Y is sufficiently small to prevent or greatly reduce the likelihood of bronchial wall tissue being caught or pinched between the flange 910 and the housing 850 during withdrawal of the delivery catheter 110. This eliminates the possibility of the flange 910 catching or lodging on the bronchial tissue during removal of the delivery catheter 110.

Actuation Handle

There is now described an actuation handle for the delivery catheter that can be used to slide the outer shaft 820 (and the attached housing 850) relative to the inner shaft 825 while maintaining the inner shaft 825 stationary relative to the handle. Figure 15 shows a side view of an actuation handle 1510. In the illustrated embodiment, the actuation handle 1510 has an elongate shape suitable for grasping within an operator's hand. It should be appreciated, however, that the shape of the actuation handle 1510 can vary. The actuation handle 1510 includes an actuation member, such as a slidable actuation slider 1515, that can be actuated to slide the outer shaft 820 relative to the inner shaft

825 (the inner shaft is not shown in Figure 15) during ejection of the bronchial isolation device 115. The actuation member can be positioned on the handle 1510 such that an operator can grasp the handle with a single hand and also move the actuation member using a finger or thumb of the same hand. For example, in the embodiment shown in Figure 15, the slider 1515 is positioned along the side of the actuation handle 1510 so that the operator's thumb can be used to move the slider 1515. Other configurations can be used.

Figure 16 shows a cross-sectional view of the actuation handle 1510, which includes an actuation system for moving the outer shaft relative to the handle. In one embodiment, the actuation system comprises a rack and pinion system for effecting movement of the outer shaft 820 relative to the inner shaft 825. The actuation slider 1515 is coupled to the actuation system. The actuation slider 1515 is slidably positioned inside an elongate slot 1605 in the actuation handle 1510. A distal end of the actuation slider 1515 abuts or is attached to a first rack 1610 that is also slidably mounted in the elongate slot 1605. The first rack 1610 has a first edge with teeth that mesh with corresponding teeth on a first pinion 1615. The first pinion 1615 is engaged with a second pinion 1620 having teeth that mesh with a second rack 1625 mounted in an elongate slot 1628. The second rack 1625 is attached to the outer shaft 820 of the delivery catheter 110 such that movement of the second rack 1625 corresponds to movement of the outer shaft 820. That is, when the second rack slidably moves in the proximal direction or distal direction, the outer shaft 820 also moves in the proximal or distal direction, respectively. The inner shaft 825 is fixedly attached to the handle 1510, such as by using adhesive or through a friction fit. The first rack, second rack, first pinion, and second pinion collectively form a rack and pinion system

that can be used to transfer distal movement of the actuation slider 1515 to proximal movement of the outer shaft 820 while the inner shaft 825 remains stationary relative to the handle 1510, as described below.

The actuation slider 1515 can be positioned in an initial position, as shown in Figure 16. When the actuation slider 1515 is in the initial position, the flange 910 is fully withdrawn inside the housing 950 (as shown in Figure 13). In one embodiment, the actuation slider 1515 is at the proximal end of the handle when in the initial position, although it should be appreciated that the initial position can vary. When the actuation slider 1515 slidably moves in the distal direction (represented by the arrow 1630 in Figure 16) from the initial position, the rack and pinion system causes the outer shaft 820 to slidably move in the proximal direction (represented by the arrow 1635 in Figure 16), and vice-versa, while the inner shaft 825 remains stationary relative to the handle. More specifically, movement of the actuation slider 1515 in the distal direction 1630 moves the rack 1610 in the distal direction, which drives the first pinion 1615 and which, in turn, drives the second pinion 1620. The gearing between the second pinion 1620 and the second rack 1625 causes the second rack 1625 to move in the proximal direction 1635 through the slot 1628. As mentioned, the second rack 1625 is attached to the outer shaft 820 so that the outer shaft 820 moves in the proximal direction 1635 along with the second rack 1625. During such movement, a distal region of the outer shaft 820 slides into the handle 1510. While this occurs, the inner catheter 825 (which is fixed to the handle 1510) remains stationary relative to the handle 1510 while the outer shaft 820 moves. Thus, when the operator moves the slider 1515 in the distal direction 1630, the outer shaft 820 (and the attached housing 850) slides in the proximal direction, with the inner shaft 820

and flange 910 remaining stationary relative to the handle. The handle can be fixed relative to the patient such that the handle, inner shaft, flange and bronchial isolation device remain fixed relative to the patient during ejection of the bronchial isolation device from the housing.

The gear ratio between the first pinion 1615 and second pinion 1620 can be varied to result in a desired ratio of movement between the actuation slider 1515 and the outer catheter 820. For example, the first pinion 1615 can have a larger diameter than the second pinion 1620 so that the outer shaft 820 (and the attached housing 850) are withdrawn in the proximal direction at a slower rate than the actuation slider 1515 is advanced in the distal direction. The gear ratio can also be varied to reduce the force required to move the actuation slider 1515 and thereby make it easier for an operator to control ejection of the bronchial isolation device 115 from the housing 850. The ratio between the pinions can be altered to make the withdrawal of the outer shaft faster, slower, or the same speed as the actuation slider movement. In one embodiment, the rack and pinion system is configured such that a 2:1 force reduction occurs such that the actuator slider moves about twice the distance that the outer shaft 820 is moved. For example, if the slider is moved an inch in the distal direction, then the outer shaft and the attached housing moves about half an inch in the proximal direction, and vice-versa.

The handle 1510 can include a safety lock that retains the actuation slider 1515 (or any other type of actuation member) in the initial position until the operator applies a force to the actuation slider sufficient to disengage the safety lock. The safety lock prevents inadvertent deployment of the bronchial isolation device either by inadvertent movement of the actuation slider in the distal

direction or by inadvertent movement of the outer shaft 820 in the proximal direction relative to the handle. Inadvertent proximal movement of the outer shaft 820 can possibly occur when the delivery catheter 110 is being advanced into the patient's trachea, which can cause resistance to be applied to the outer shaft 820 by an anesthesia adaptor valve, endotracheal tube, or the lung.

In one embodiment, the safety lock comprises one or more magnets positioned in the actuation handle 1510. Figure 17 shows a partial, cross-sectional view of the proximal end of the handle 1510 with the actuation slider 1515 positioned distally of the initial position. A first magnet 1710 is located on the handle 1510 near the initial location of the actuation slider 1515. A second magnet 1715 is located on or in the actuation slider 1515. The magnets 1710, 1715 are oriented such that an attractive magnetic force exists therebetween. When the actuation slider 1515 is in the initial position, the magnetic force between the magnets 1710, 1715 retains the actuation slider 1515 in the initial position until the operator applies a force to the slider 1515 sufficient to overcome the magnetic force and move the slider 1515 out of the initial position.

It should be appreciated that configurations other than magnets can be employed as the safety lock. One advantage of magnets is that the attractive force between the magnets 1710, 1715 automatically increases as the actuation slider moves toward the initial position. If the actuation slider happens to be out of the initial position when the bronchial isolation device is loaded into the housing 850, the actuation slider 1515 is driven back toward the initial position as the bronchial isolation device is loaded into the housing 850. The magnetic attraction between the first and second magnets 1710, 1715 automatically

engages the safety lock when the actuation slider 1515 moves into the initial position.

The safety lock can include an additional feature wherein the operator must depress the actuation slider 1515 in order to disengage the slider from the initial position. As shown in Figure 17, the slot 1605 in the actuation handle 1510 has an opening 1712. The actuation slider 1515 moves outward and sits in the opening 1712 when in the initial position. The operator must depress the slider 1515 to move the actuation slider 1515 out of the opening in order to disengage the slider from the initial position and slide the actuation slider 1515 in the distal direction.

Adjustment of Handle Position Relative to Bronchoscope

As discussed above, according to the transcopic delivery method, the bronchoscope 120 (shown in Figures 1, 6, 7) is used in deploying the delivery catheter 110 into the bronchial passageway. Pursuant to this method, the delivery catheter 110 is inserted into the working channel 710 of the bronchoscope 120 such that the delivery catheter's distal end is aligned with or protrudes from the distal end of the bronchoscope 120. The bronchoscope 120, with the delivery catheter 110 positioned as such, is then inserted into the bronchial passageway via the patient's trachea such that the distal end of the delivery catheter is positioned at a desired location in the bronchial passageway, as shown in Figure 1. It should be appreciated that the delivery catheter 110 can be inserted into the bronchoscope 120 either before or after the bronchoscope has been inserted into the bronchial passageway.

Figure 18 shows an enlarged view of the distal region of the bronchoscope 120 with the delivery catheter's distal end (including the housing 850) protruding

outward from the working channel 710. The bronchial isolation device 115 is positioned within the housing 850. The bronchial isolation device 115 is a distance D from the distal end of the bronchoscope 120. Once the bronchoscope and delivery catheter are in the patient, the operator may desire to adjust the distance D to fine tune the location of the bronchial isolation device 115. However, it can also be desirable or even required to hold the actuation handle 1510, and thus the inner shaft 825, stationary relative to the bronchoscope 120. This way, the bronchoscope 120 can be fixed relative to the patient's body, thereby keeping the bronchial isolation device 115 fixed relative to the target location in the bronchial passageway.

Figure 19 shows another embodiment of the actuation handle, referred to as actuation handle 1910, that can be used for transcopic delivery and that can be fixed relative to a bronchoscope while also allowing for adjustments in the distance D of Figure 18 once the delivery device is positioned in the bronchoscope. The actuation handle 1910 includes an actuation member in the form of a button 1915 that can be depressed in the distal direction to move the outer shaft 820 of the delivery catheter in the proximal direction. The handle includes an adjustment mechanism that is used to adjust the position of the handle relative to the bronchoscope. The adjustment mechanism comprises an elongated bronchoscope mount 1920 that extends outwardly from the distal end of the actuation handle 1910 and extends at least partially over the catheter outer shaft 820 such that the outer shaft can slide freely within the bronchoscope mount 1920. The bronchoscope mount 1920 extends outward from the handle a distance A. The bronchoscope mount 1920 is slidably moveable into or out of the handle 1910 such that it can be pushed into or pulled out of the handle 1910

along the axis of the mount 1920 in order to adjust the distance A. In one embodiment the bronchoscope mount 1920 is biased outward, for example with a spring, so that its tendency is to be fully extended outward from the handle 1910. A locking mechanism includes a lock, such as a lever 1925, that can be depressed to lock the bronchoscope mount 1920 relative to the handle 1910 when the distance A is adjusted to a desired amount, as described below. Once the distance A is at a desired amount, the operator can lock the bronchoscope mount 1920 relative to the handle to fix the bronchoscope mount 1920 relative to the handle 1910.

With reference to Figure 20, the bronchoscope mount 1920 has a size and shape that is configured to sit within the entry port 135 of the bronchoscope working channel. In use, an operator can insert the bronchoscope mount 1920 into the entry port 135 such that it abuts and sits within the entry port 135. In this manner, the actuation handle 1910 is fixed relative to the bronchoscope 120 with the catheter's distal end protruding a distance D from the bronchoscope's distal end (as shown in Figure 20). The operator can then adjust the distance A by moving the bronchoscope mount 1920 into or out of the handle 1910, such as by pushing on the handle 1910 to decrease the distance A. By virtue of the outer and inner catheter shafts' attachment to the handle, adjustments in the distance A will correspond to adjustments in D. That is, as the operator decreases the distance A (Figure 20), the catheter slides deeper into the bronchoscope so that the distance D (Figure 18) increases, and vice-versa.

Once the desired distance A has been achieved, the bronchoscope mount 1920 is locked by depressing the lever 1925. Thus, by adjusting the distance A, the operator also adjusts the distance D (shown in Figure 18) between the distal

end of the bronchoscope 120 and the bronchial isolation device 115. This can be helpful where different brands or types of bronchoscopes have different length working channels. It also allows the operator to fine-tune the position of the housing 850 and bronchial isolation device in the bronchial passageway without moving the bronchoscope. Other mechanisms for locking the movement of the bronchoscope mount 1920 are possible such as depressing and holding the lever 1925 to release the movement of the bronchoscope mount 1920, repositioning the bronchoscope mount 1920, and releasing the lever 1925 to lock the bronchoscope mount 1920 in place.

Catheter Sheath

As discussed above, during use of the delivery catheter 110 it can be desirable to fix the location of the inner shaft 825 (and thus the bronchial isolation device in the housing 850) relative to the patient's body while proximally withdrawing the outer shaft 820 and the housing 850 relative to the bronchial passageway to eject the bronchial isolation device, as shown in Figures 11A and 11B. Given that the outer shaft 820 moves proximally relative to the bronchial passageway during the foregoing process, the outer shaft 820 can encounter resistance to proximal movement due to friction with devices or body passageways in which the delivery device is positioned. For example, the outer surface of the outer shaft 820 can encounter frictional resistance against an anesthesia adaptor through which the outer shaft is inserted. The anesthesia adapter is a fitting that permits the bronchoscope and delivery catheter to be inserted into the lung without leakage of ventilated oxygen, anesthesia gases, or other airway gases. The adapter typically has a valve through which the delivery catheter or bronchoscope is inserted. The valve seals against the outer surface

of the outer shaft 820 to prevent air leaks. This seal can provide resistance against proximal movement of the outer shaft 820 during ejection of the bronchial isolation device from the housing 850. Such resistance to proximal movement of the outer shaft 820 is undesirable, as it can result in the bronchial isolation device 115 being deployed in a location distal of the target location in the bronchial passageway.

Figure 21 shows an embodiment of the delivery catheter 110, which includes a deployment sheath 2110 that reduces or eliminates the resistance to proximal movement of the catheter outer shaft 820 during ejection of the bronchial isolation device 115. The deployment sheath 2110 is a sheath having an internal lumen in which the outer shaft 820 is slidably positioned. The sheath 2110 is fixed at a proximal end 2112 to the actuation handle 815. Figure 21 shows the actuation handle 815, although the sheath 2110 can be used with any type of handle. Furthermore, it should be appreciated that the sheath 2110 is not limited to use with delivery catheters that deploy bronchial isolation devices, but can rather be used with various types of catheters. For example, the sheath configuration can be used in combination with catheters suitable for use in venous, arterial, urinary, billiary, or other body passageways. The sheath 2110 extends over the outer shaft 820 a distance X. The distance X can vary. In one embodiment, the distance X is long enough to extend to locations where the outer shaft is likely to encounter frictional resistance to movement, such as at the anesthesia adapter, if present. However, when used with a delivery catheter having a housing 850, the distance X is such that the distal end of the sheath does not interfere with the housing 850 being fully withdrawn in the proximal direction.

The sheath 2110 can have a very thin wall to minimize its contribution to the overall diameter of the delivery catheter 110. In one embodiment, the sheath 2110 has a wall thickness in the range of approximately 0.002 inches to approximately 0.004 inches. The sheath 2110 is manufactured of a material that is lubricous to minimize resistance to the outer shaft 820 sliding inside the sheath 2110. The sheath material also has a stiffness that resists crumpling when a compressive load is placed along the length of the sheath (such as when the sheath is possibly pinched or grabbed to fix its position relative to the anesthesia adapter during ejection of the catheter from the housing, as described below). The compressive forces can come from the possibility that the outer shaft is pinched when the sheath is pinched, and thus when the handle is actuated and the outer shaft starts to move towards the handle, the sheath is compressed]. The sheath 2110 can be manufactured of various materials, such as, for example, polyimide, Teflon doped polyimide, PolyEtherEtherKetone (PEEK), etc.

In use, the delivery catheter 110 is positioned in the patient's lung through the trachea, such as described above. This can involve the delivery catheter 110 being positioned through a device such as a bronchoscope or through an anesthesia adapter 2210, such as shown in the partial view of Figure 22. The sheath 2110 is located between the anesthesia adapter 2210 and the outer shaft 820 (not shown in Figure 22) such that the sheath 2110 provides a lubricous shield between the outer shaft 820 and the anesthesia adapter. Thus, the outer shaft 820 can be proximally moved using the actuation handle without the outer shaft 820 encountering frictional resistance from contact with the anesthesia adapter (or any other object or device in which the sheath and outer shaft are positioned). If desired, the operator can grab or pinch the catheter 110 (as

represented by the arrows 2215 in Figure 22) through the sheath 2110 at the entrance of the anesthesia adapter 2210 to fix the location of the sheath 2110 (and thus the location of the handle and the inner shaft) relative to the patient and/or anesthesia adaptor. As the sheath 2110 is made of a relatively rigid and lubricous material, the outer shaft 820 is free to slide through the sheath in the proximal direction as the sheath is grabbed.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.